

CEO AGM address to shareholders

Good morning,

I am proud to say, on behalf of our extended team, that 2021 was a significant year of innovation, research, and development for Incannex. Our Company has remained nimble and resilient to challenges associated with the covid-19 pandemic and we begin the new year in a strong financial and operational position.

Our focus for 2022 is now on our pipeline of candidates being assessed in clinical trials. These trials are informed by the groundwork completed over the past two years which includes our extensive R&D work and advice we have received from regulators, including the US Food and Drug Administration (“FDA”).

There’s an increasing body of scientific literature that indicates that the best use of cannabinoids is to combine them with existing pharmaceutical drugs to produce better patient outcomes by either improving product safety, efficacy, or both. At Incannex, we are the first mover globally to formally develop sophisticated cannabinoid combination drugs as a business strategy.

Upon proving synergy in our compounds in pre-clinical activities, we have been able to aggressively pursue patent protection over our three preferred unique combination compounds before competitors have been able to do so. This has opened significant economic potential over a broad range of indications.

In quarter one of this year, we anticipate the receipt of results from our most important research activities undertaken to date. Patient dosing in our phase 2 clinical trial investigating IHL-42X for the treatment of obstructive sleep apnoea (“OSA”) was completed in December. The preliminary report from that study is anticipated imminently as we await it to be handed down from the independent trial manager, Novotech.

We have been highly impressed with the professionalism of Novotech and our partners at the University of Western Australia and The Alfred Hospital who worked together to conduct the multi-site trial using our product. OSA is a disease for which there is no available pharmacological solution. Existing patient solutions are under-utilised because they are cumbersome and it’s a condition that affects approximately 30 million adults in the United States alone.

After a considerable period of assessment, our in vivo studies on the use of IHL-216A to lessen the effects of traumatic brain injury (“TBI”) are nearing conclusion. Precursory studies completed in 2020 indicated that our compound reduced neuronal damage in the hippocampal region of the brain by at least 53% more effectively than CBD alone. This outcome led us to partner with the Monash Trauma Group at the department

of neuroscience at Monash University in March of 2021 to commence an extensive “stage 2” level animal study.

This study employed a model of traumatic brain injury that was developed in collaboration with the US National Football League and will ensure the that results will be globally recognisable when delivered. Clinical trial activities are already planned to follow this study.

Another key focus of our business is to ensure that we are highly engaged with the FDA both prior to and during our clinical studies. This closeness is key to our strategy to pursue the most efficient pathways to achieve FDA registration and marketing approval for no less than six medical indications that in one way or another have patient cohorts with unmet medical needs.

Last quarter, we received both written responses and responses via teleconference from FDA that were positive, constructive, and supportive of our “psi-GAD” program, a cutting-edge and world first therapy that combines the use of psilocybin with psychotherapy to treat patients with Generalised Anxiety Disorder (“GAD”). The FDA confirmed that the clinical strategy for the development of our psilocybin-assisted therapy for GAD is appropriate and they also conveyed a genuine interest in the use of psilocybin for anxiety under controlled conditions with trained psychotherapists. Australian human research ethic’s approval to commence our phase 2 study has been received, clearing the way for patient recruitment to commence imminently now that our psychotherapists have completed training.

FDA pre-IND guidance was also received in 2021 for IHL-675A, our proprietary combination multi-use cannabinoid compound, following [6] different in vitro and in vivo studies using established disease models relevant to inflammatory disorders including; rheumatoid arthritis, lung inflammation conditions and inflammatory bowel disease. In each of these models, our compound outperformed CBD in suppressing inflammation. This is a startling and exciting finding when we consider the global attention given to CBD as a potential anti-inflammatory. A phase 1 study for IHL-675A is scheduled to commence in the current quarter using IHL-675A GMP-grade soft gel capsules.

During the year, Incannex raised \$17M from investors, including \$8M from our chief medical officer Dr Sud Agarwal. With a current cash balance of circa \$20 million, Incannex is fully funded to undertake the necessary clinical development activities for each of our compounds and therapies.

Considering weakened market conditions on the Nasdaq and more specifically the Nasdaq Biotech Index, which has corrected circa 20% in recent months, we have decided to complete our Nasdaq listing without an associated capital raise so that all variables associated with listing are under the Company’s control.

We have adjusted our strategy towards a “compliance listing”, which is now expected to occur during February and will coincide with the release of results from our IHL-42X phase 2 clinical study. After listing on Nasdaq with ticker “IXHL”, the Company reserves the right to raise capital at an appropriate time and to the

appropriate suite of investors, as guided by our US financial partners EAS Advisors and Roth Capital. We believe this decision will allow us to time any capital raising initiative to take advantage of improved market conditions. Additionally, we will have the opportunity to announce further developments regarding our clinical programs and potentially new research programs in the psychedelic therapy field as our relationships within that space mature.

To strengthen our US presence, we are in the process of establishing an office there to undertake strategic stakeholder engagement with clinical research facilitators, regulatory authorities, and the investment community. I personally will be spending an extended period of time in the US from the end of this month to set up our US office and networks. Additionally, we have engaged Rx communications, a top tier New York based PR firm, and together we have implemented an extensive PR plan leading into and post our Nasdaq listing to continue to drive awareness throughout the broader US market.

The Board of Directors is also currently contemplating a free bonus option entitlement to reward all of our loyal shareholders. At this point no definitive decision has been made as to the terms of the bonus issue but the Company will provide an update to market once the board has reached a decision.

Finally, I would like to thank the Incannex Board, management, research, and advisory teams for their dedication, focus and energy over the past 12 months. I'd also like to thank our shareholders for their outstanding support as we collectively work towards bringing forward a range of innovative medicines and therapies to the public.

Thank you,
Mr Joel Latham, CEO and Managing Director.

ENDS

The release of this announcement has been approved for issue by IHL's Board of Directors. For further details on the announcement, interested parties should contact:

Mr Joel Latham, Managing Director and Chief Executive Officer
P: +61 409 840 786
E: joel@incannex.com.au